

technology and services. The EHR exception and safe harbor require that the software be “interoperable” as defined in the regulations. The rules also provide that certain software will be deemed to be “interoperable” if that software has been certified by a certifying body recognized by the Secretary within 12 months prior to the donation. Under the interim guidance for the recognition of certifying bodies published by the ONC (“Office of the National Coordinator for Health Information Technology (ONC) Interim Guidance Regarding the Recognition of Certification Bodies”), for an organization to be recognized as a recognized certifying body (RCB), the organization must, among other characteristics:

- Have in place a demonstrated process for and experience in certifying products to be in compliance with criteria recognized by the Secretary;
- Have a method by which it can incorporate all applicable standards and certification criteria recognized by the Secretary into its certification processes; and

- Have the ability to adapt its processes to emerging certification criteria recognized by the Secretary.

The RCBs would therefore have to certify such products in conformity with, among other provisions, these Interoperability Standards, once recognized, for the certified products to be deemed interoperable under the physician self-referral exception and anti-kickback safe harbor, respectively, and, thus, eligible for donation to certain health care providers under the physician self-referral law and the anti-kick back statute.

The Department is mindful that the ability of software to be interoperable evolves as technology develops. Consequently, if an enforcement action is initiated for an allegedly improper donation of EHR non-certified software, the Department would review whether the software was interoperable at the time of donation, as defined in the regulations. The Department would consider the prevailing state of technology at the time the items or services were provided to the recipient. As explained in the regulations, the Department understands that parties should have a reasonable basis for determining whether the EHR software is interoperable. We therefore indicated that “it would be appropriate—and, indeed, advisable—for parties to consult any standards and criteria related to interoperability recognized by the Department.” Compliance with these standards and criteria, as we explained in the regulations, “will provide greater

certainty to donors and recipients that products meet the interoperability requirement, and may be relevant in an enforcement action.” (See 71 FR 45156 and 71 FR 45127.)

The Department believes that the one-year period between acceptance in January 2008 and recognition in January 2009 provided both the public and private sectors with adequate time to review, test, and provide input on the identified HITSP Interoperability Specifications prior to their recognition. Based on the above, the Secretary has now recognized these HITSP Interoperability Specifications.

FOR FURTHER INFORMATION CONTACT:

Judith Sparrow at (202) 690-7151.

Dated: January 14, 2009.

Marc R. Weisman,

Executive Director, Office of the National Coordinator for Health Information Technology.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Healthcare Infection Control Practices Advisory Committee (HICPAC)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting for the aforementioned committee:

Times and Dates: 9 a.m.–5 p.m., February 12, 2009.

9 a.m.–12 p.m., February 13, 2009.

Place: Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, Atlanta, Georgia 30333, Global Communications Center, Bldg. 19, Auditorium B3.

Status: Open to the public, limited only by the space available.

Purpose: The Committee is charged with providing advice and guidance to the Secretary, the Assistant Secretary for Health, the Director, CDC, and the Director, National Center for Preparedness, Detection, and Control of Infectious Diseases (NCPDCID), regarding (1) The practice of hospital infection control; (2) strategies for surveillance, prevention, and control of infections (e.g., nosocomial infections), antimicrobial resistance, and related events in settings where healthcare is provided; and (3) periodic updating of guidelines and other policy statements regarding prevention of healthcare-associated infections and healthcare-related conditions.

Matters to be Discussed: The agenda will include a follow up discussion of Health and Human Services Healthcare-Associated

Infections (HAI) elimination plan, Norovirus Guideline and Healthcare worker vaccination update.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information:

Wendy Vance, HICPAC, Division of Healthcare Quality Promotion, NCPDCID, CDC, 1600 Clifton Road, NE., Mailstop D-10, Atlanta, Georgia 30333 Telephone (404) 639-2891.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: January 12, 2009.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Rescission of February 4, 2004, Order and Subsequent Amendments Prohibiting the Importation of Birds and Bird Products From Specified Countries

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS) is announcing its intent to rescind its February 4, 2004 order and subsequent amendments prohibiting the importation of birds and bird products from specified countries based on the threat that imports from such countries increases the risk that highly pathogenic avian influenza H5N1 may be introduced into the United States. After consideration of public comment, CDC will publish a final notice regarding these prohibitions. The U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) has implemented and continues to enforce regulations to prohibit or restrict the importation of birds, poultry, and unprocessed birds and poultry products from regions that have reported the presence of highly pathogenic avian influenza H5N1 in poultry. See 9 CFR 93.101, 93.201, 94.6, & 95.30. While USDA/APHIS actions are based primarily on protecting the U.S.